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(54) Endovascular grafting apparatus, system and method and devices for use therewith.

(57) Endovascular grafting system having a capsule catheter (12) comprising a flexible elongate tubular member (16) having proximal and distal extremities and a capsule (36) mounted on the distal extremity of the tubular member (16). The capsule (36) is generally cylindrical in shape and is formed of a helical wrap of a metal ribbon (39). The wraps are bonded into a unitary capsule permitting bending of said unitary capsule. A graft is disposed within the capsule (36). The graft is comprised of a tubular member having proximal and distal ends. Hooks are secured to the proximal and distal ends of the tubular member and face in a direction outwardly towards the inner wall of the capsule. A push rod is disposed within the capsule catheter (12) and engages the graft whereby upon relative movement between the push rod and the capsule catheter, the graft can be forced out of the capsule.

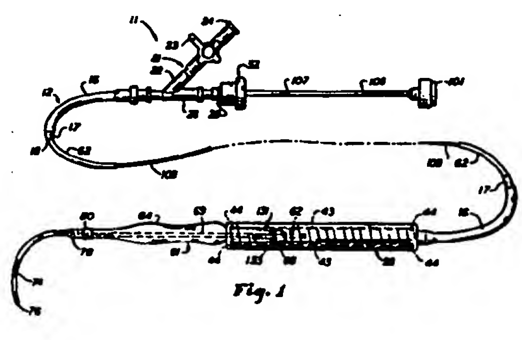
Fig. 1

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This application relates to endovascular grafting apparatus, system and method and devices for use therewith.

The state of the art is described in the background of the invention in U.S Patent No. 4,787,899. In addition WO 89/08433 discloses an intraluminal grafting system which includes a hollow graft and which has a proximal and distal staple. The system includes a capsule for transporting the graft through the lumen and for positioning the graft upstream in a lumen which may be a blood vessel or artery. A tube is connected to the capsule and extends to the exterior of the vessel for manipulation by the user. A catheter is positioned within the tube and is provided with an inflatable membrane which is in communication via a channel with inflation and deflation means. With the inflatable membrane deflated, the capsule is positioned in the lumen and manipulated to a desired location. Upon inflation, the force exerted by the Inflatable membrane and the structure of the staples urges the staples into the vessel, retaining the graft in position

In general, it is an object of the present invention to provide an endovascular grafting apparatus, system and method and devices for use therewith which overcome the disadvantages of the prior art appartus, systems and devices.

Advantageously embodiments of the invention provide an apparatus and system of the above character which utilizes a pusher rod assembly which is constrained so that relatively great forces can be applied by the pusher rod assembly.

Advantageously embodiments of the invention provide an apparatus and system of the above character in which the capsule is sufficiently flexible so that it can negotiate bends in the vessels of a patient.

Advantageously embodiments of the invention provide a grafting apparatus and system which utilizes a flexible capsule which can contain a graft with hook-like elements without any danger of the hook-like elements penetrating the capsule.

Advantageously embodiments of the invention provide an apparatus and system of the above character in which the graft automatically springs into an open or expanded position when it is released from the capsule.

Advantageously embodiments of the invention provide an apparatus, system and method of the above character in which a pushing force is applied to the distal extremity of the balloon for advancing a graft out of the capsule.

Advantageously embodiments of the invention provide an apparatus and system of the above character in which a fixed wire or an over-the-wire guide wire system can be used.

Advantageously embodiments of the invention provide an apparatus and system of the above character in which the graft can be compressd to a very small size in a flexible capsule.

According to a first aspect of the present invention there is provided in an endovascular grafting system, a capsule catheter comprising a flexible elongate tubular member having proximal and distal extremities and a capsule mounted on the distal extremity of the tubular member, said capsule being generally cylindrical in shape and being formed of a helical wrap of a metal ribbon and means bonding said wraps into a unitary capsule while permitting bending of said unitary capsule, a graft disposed within the capsule, the graft comprising a tubular member having proximal and distal ends, hook-like attachment means secured to the proximal and distal ends of the tubular member and facing in a direction outwardly towards the inner wall of the capsule and push rod means disposed within the capsule catheter and engaging the graft whereby upon relative movement between the push rod means and the capsule catheter, the graft can be forced out of the capsule.

Advantageously the system may further include a balloon catheter comprised of a flexible elongate member having proximal and distal extremities and a balloon secured to the distal extremity of the flexible elongate member, the flexible elongate member of the balloon catheter having a balloon inflation lumen extending through the flexible elongate member of the capsule catheter and means for inflating and deflating the balloon through the balloon inflation lumen of the flexible elongate member of the balloon catheter.

Advantageously said balloon catheter includes a rigid metallic tube extending through the balloon and in communication with the balloon inflation lumen. Preferably said push rod means includes a wire extending through said rigid metallic tube. Preferably said balloon catheter includes a plug distal of the balloon engageable by said wire.

Advantageously the system may further include a pusher button mounted on the flexible elongate member of the balloon catheter and engaging the graft. Preferably the pusher rod engages the pusher button. In another arrangement said pusher button is mounted in a fixed position on the flexible elongate member of the balloon catheter. In yet another arrangement said pusher button is mounted on said flexible elongate member with the balloon catheter so that it is movable between one position spaced from the proximal extremity of the balloon and another position adjacent to the proximal extremity of the balloon.

According to a second aspect of the present invention there is provided a capsule catheter comprising, a flexible elongate element having proximal

and distal extremities, a capsule mounted on the distal extremity, said capsule being formed of helical wraps of a metal ribbon to provide a cylindrical capsule and means engaging said wraps for retaining said wraps in said cylindrical capsule to prevent discontinuities occurring in said wraps when said capsule is bent through angles ranging up to approximately 120°.

Advantageously the capsule catheter may further include a plurality of spaced apart flexible elongate elements extending longitudinally of the capsule exterior of the capsule and secured to the proximal and distal extremities of the capsule for preventing separation of the wraps of the capsule upon bending of the capsule. Preferably said flexible elongate elements are formed of Kevlar.

Advantageously the metal ribbon is stainless steel.

Advantageously the capsule catheter may further include an inner tubular lumen disposed within said flexible elongate element and means carried by the flexible elongate element for retaining said inner liner within said flexible elongate element. Preferably the capsule catheter may further include a fitting carried by the proximal extremity of the flexible elongate element for introducing a fluid through the flexible elongate element.

Advantageously the capsule has a diameter ranging from .20 to .300 inches and has a length ranging from 8 to 20 centimetres.

Advantageously said ribbon has a thickness of .002 to .005 inches and a width of approximately .150 inches.

Advantageously the capsule catheter may further include a sheath of heat shrinkable material extending over the exterior of the helical wraps.

According to a third aspect of the present invention there is provided a balloon catheter assembly comprising a flexible elongate element having a balloon inflation lumen extending therethrough, said flexible elongate element having proximal and distal extremities, a balloon having proximal and distal extremities carried by the distal extremity of the flexible elongate element and a rigid tubular member extending through the balloon and having a bore therein in communication with the lumen in the flexible elongate element, the interior of the balloon being in communication with the distal extremity of the rigid tubular member.

Advantageously the balloon catheter may further include a fixed guide wire formed of a coil spring and having a proximal extremity and means securing the proximal extremity of the guide wire to the distal extremity of the balloon.

Advantageously the balloon catheter may further include a pusher button carried by the flexible elongate member and stop means preventing movement of said pusher button longitudinally of the flexible elongate member beyond a predetermined location spaced from the proximal extremity of the balloon but permitting movement of such pusher button between said predetermined location and the proximal extremity of the balloon. Preferably there is also provided an additional stop means for preventing longitudinal movement from the predetermined location. In another arrangement said flexible elongate member is formed of an irradiated plastic and said stop means is formed from said irradiated plastic.

Advantageously the balloon catheter may further include plug means carried by the distal extremity of the balloon.

According to a fourth aspect of the present invention there is provided a pusher rod assembly for use with an elongate catheter comprising a metal elongate tubular member having proximal and distal extremities and having a bore extending therethrough, a knob secured to the proximal extremity and adapted to be grasped by a human hand.

Advantageously the pusher rod assembly may further include a flexible wire secured to the tubular member extending centrally through the bore in said tubular member and having a length so that it extends beyond the length of the tubular member. Preferably said pusher rod has an inside diameter of .053 inches and said wire has a diameter of .018 inches. Preferably said tubular member and said wall are formed of stainless steel.

According to a fifth aspect of the present invention there is provided an expandable intraluminal vascular graft for implanting in a body vessel comprising a deformable tubular member having proximal and distal ends and a wall extending between the proximal and distal ends, the wall being formed of a flexible material capable of receiving tissue ingrowth, said tubular member being capable of assuming a first position of reduced size for insertion into the body vessel and a second expanded position, expandable yieldable spring means secured to the proximal and distal extremities of the tubular member, said yieldable spring means urging said tubular member from said first position of reduced size to a second expanded position and attachment means secured to said expandable spring means for attachment to the body vessel.

Advantageously said expandable spring means is in the form of substantially vee-shaped spring portions having apices and legs extending from the apices, the spring means having a helical torsion spring at each apex yieldably urging said legs in a direction to open the vee-shaped spring portions.

Advantageously said expandable spring means includes a plurality of interconnected vees with each vee having an apex and with coil spring

means formed at each apex serving to expand the vees in an outward direction along the plane of each of the vees.

Advantageously the attachment means is in the form of hook-like elements secured to the spring means in the vicinity of the apices of the vees. Preferably the apices of the vees lie in first and second planes spaced longitudinally of the longitudinal axis of the graft. Preferably the apices in the first and second planes are spaced beyond the end of the tubular member and the hook-like elements are mounted on the vees in the vicinity of the apices lying in the first and second planes. Preferably the apices in the first and second planes are offset circumferentially with respect to the apices in the other of the first and second planes. Preferably at least three apices are provided in the first plane and at least three apices are provided in the second plane.

Advantageously the graft may further include radiopaque marker means secured to the wall of the tubular member, said marker means including first and second aligned radiopaque markers spaced apart longitudinally of the tubular member to permit ascertaining whether any twisting of the tubular member has occurred. Preferably the first and second markers are positioned adjacent apices of the yieldable spring means.

According to a sixth aspect of the present invention there is provided a pusher rod assembly for use with an elongate catheter comprising a metal elongate tubular member having proximal and distal extremities and having a bore extending therethrough and a knob adapted to be grasped by the hand secured to the proximal extremity of the tubular member, said knob having a hole therein in registration with the bore in the tubular member.

Advantageously the pusher rod assembly may further include a flexible guide wire extending through the bore in the elongate tubular member and through the hole in the knob.

According to a seventh aspect of the present invention there is provided a pusher rod assembly for use with an elongate catheter comprising a metal elongate tubular member having proximal and distal extremities and having a bore extending therethrough, an adapter secured to the proximal extremity of the elongate tubular member, said adapter having a hole extending therethrough, a flexible wire extending through the bore in the tubular member and extending through the hole in the adapter, the wire having proximal and distal extremities and a knob secured to the proximal extremity of the wire.

According to an eighth aspect of the present invention there is provided an expandable intraluminal vascular graft for implanting in a body vessel comprising a deformable tubular member having proximal and distal extremities and a wall extending between the proximal and distal extremities, the wall being formed of a flexible material capable of receiving tissue ingrowth, attachment means secured to the proximal and distal extremities of the deformable tubular member, said attachment means at the proximal extremities including hook-like elements spaced circumferentially around the proximal extremity and having protrusions extending therefrom at an angle ranging from 55° to 80° from the longitudinal and in a direction which is facing toward the distal extremity of the tubular member, the attachment means for the distal extremity including hook-like elements spaced circumferentially around the distal extremity and having projections extending therefrom which are inclined from the vertical by 30° to 90° in a direction facing towards the proximal extremity of the tubular member so that the hook-like elements on the proximal and distal extremities face towards each other to facilitate holding the graft in place in the vessel.

According to a ninth aspect of the present invention there is provided a method for implanting an expandable intraluminal vascular graft into a body vessel of a patient, by the use of a capsule catheter comprising a flexible elongate tubular member having proximal and distal extremities and a capsule mounted on the distal extremity of the tubular member, a graft having proximal and distal extremities and having hook-like attachment means secured to the proximal and distal extremities, said graft being compressed within said tubular member, a balloon catheter comprised of a flexible elongate member having proximal and distal extremities and a balloon secured to the distal extremity of the flexible elongate member and a pusher button secured to the flexible elongate member of the balloon catheter and spaced from the proximal extremity of the balloon with the flexible elongate member of the balloon catheter extending through the capsule, through the graft and through the flexible elongate member of the capsule catheter and positioned so that the pusher button is disposed within the graft and the capsule catheter and with the balloon being disposed outside of the capsule catheter and a pusher rod assembly, the method comprising the steps of advancing the pusher rod assembly along the flexible elongate tubular member of the capsule catheter and causing a force to be applied to the pusher button by relative movement between the proximal extremity of the graft within the capsule and the capsule to cause ejection of the proximal extremity of the graft from the capsule, removing the pusher rod assembly, grasping the flexible elongate member of the balloon catheter and pulling the proximal extremity of the balloon into the graft while holding

the capsule catheter stationary and inflating the balloon to seat the attachment means carried by the proximal extremity of the graft into the vessel of the patient.

Advantageously the step of applying force to the pusher button is accomplished by using the pusher rod assembly to place a force upon the distal extremity of the balloon whereby a force is transferred from the distal extremity of the balloon through the flexible elongate member of the balloon catheter to the pusher button.

Advantageously the step of applying a force to the pusher button is accomplished by causing the pusher rod assembly to directly engage the pusher button.

Advantageously the balloon is provided with a memorized helical wrap and the balloon catheter assembly while being introduced into the vessel of the patient is rotated in the direction of the helical wrap to provide a balloon having a reduced profile during the time it is being introduced into the vessel of the patient.

According to a tenth aspect of the present invention there is provided an expandable intraluminal vascular graft for implanting in a body vessel comprising a deformable tubular member having proximal and distal extremities and a wall extending between the proximal and distal extremities, attachment means secured to the proximal and distal extremities, the attachment means including hook-like elements, the hook-like elements extending outwardly with the hook-like elements on the proximal and distal extremities face each other.

Advantageously the hook-like elements on the proximal extremity have an angle extending from the longitudinal axis ranging from •55 to 80• in a direction facing the distal extremity of the graft and wherein the hook-like elements on the distal extremity extend outwardly from the vertical in a direction ranging from 30• to 90• facing towards the proximal extremity of the graft.

Additional objects and features of the invention will appear in the following description in conjunction with the accompanying drawings.

Figure 1 is an isometric view of an endovascular grafting apparatus and system incorporating the present invention.

Figure 2 is a side elevational view partially in cross section of a capsule catheter incorporating the present invention.

Figure 3 is a side elevational view partially in cross section showing a balloon catheter assembly incorporating the present invention.

Figure 4 is a partial side elevational view in cross section of a portion off an alternative balloon catheter assembly incorporating the present invention showing the use of a movable pusher button capable of sliding over a limited range.

Figure 5 is a side elevational view partially in cross section of another alternative embodiment of a balloon catheter assembly incorporating the present invention showing the use of a movable guide wire.

Figure 6 is a cross sectional view taken along the line 6-6 of Figure 5.

Figure 7 is a side elevational view partially in cross section of a pusher rod assembly incorporating the present invention.

Figure 8 is a side elevational view partially in cross section of another embodiment of a pusher rod assembly incorporating the present invention.

Figure 9 is a cross sectional view partially in cross section showing in combination a balloon catheter and a pusher rod assembly and a movable guide wire.

Figure 10 is a side elevational view of a graft incorporating the present invention.

Figure 11 is an enlarged isometric view showing one of the spring attachment means utilized on the graft.

Figure 12 is a partial enlarged view of an alternative hook-like element utilized in the spring attachment means of Figure 11.

Figure 13 is an enlarged view showing another embodiment of a hook-like element used in the spring attachment means of Figure 11.

Figure 14 is a side elevational view partially in cross section showing the manner in which the graft is held in the capsule after ejection of the proximal extremity of the graft from the capsule.

Figure 15 is a view similar to Figure 14 but showing the proximal and distal extremities of the graft outside of the capsule with the balloon retracted so that it is within the graft and inflated to force the distal attachment means into the vessel wall.

In general, the endovascular grafting system is comprised of a capsule catheter having a flexible elongate tubular member with proximal and distal extremities and a capsule mounted on the distal extremity of the tubular member. The capsule is generally cylindrical in shape and is formed of a helical wrap of a metal ribbon. Means is provided for bonding said wraps into a unitary capsule while permitting bending of said unitary capsule. A graft is disposed within the capsule. The graft is comprised of a tubular member having proximal and distal ends. Hook-like attachment means is secured to the proximal and distal ends of the tubular member and face in a direction outwardly towards the inner wall of the capsule. Push rod means is disposed within the capsule catheter and engages the graft whereby upon relative movement between the push rod means and the capsule catheter, the graft can be forced out of the capsule.

More in particular, the endovascular grafting apparatus and system 11 and the devices for use therein are shown in Figures 1-10. This apparatus and system 11 includes a capsule catheter 12 (see Figure 2) which consists of a flexible elongate tubular member 16 formed of a suitable plastic material such as Nylon of a suitable length as, for example, 40 to 100 centimeters and preferably approximately 43 centimeters for the abdominal aortic artery and approximately 70 centimeters for the thoracic aortic artery. The tubular member 16 can have a suitable size such as an outside diameter of 4.75×10^{-3}m (.187 inches) and an inside diameter of 3.175×10^{-3}m (.125 inches). The tubular member 16 can be produced in a certain color such as blue. In order to make it radiopaque under x-rays, the flexible tubular member 16 is loaded with a suitable radiopaque material such as bismuth subcarbonate or barium sulfate. By way of example, the flexible elongate member 16 can be compounded with approximately 20% of the radiopaque material by weight.

An inner liner 17 is provided which is mounted within the tubular member 16. The liner 17 is sized so that it will fit within the tubular member 16. The liner is preferably formed of a lubricious material such as Tefzel (ethylene tetrafluoroethylene) or Teflon FEP (flourinated ethylene polypropylene). It can have an inside diameter of 2.16×10^{-3}m (.085 inches)and an outside diameter of 3.175×10^{-3}m (.125 inches) and a length as, for example, 41 centimeters which is slightly less than that of the tubular member 16. If desired, the inside diameter of the liner 17 can be in the range of 1.905×10^{-3} - 3.048×10^{-3}m (.075 to .120 inches). The liner 17 is provided with a lumen 18 which extends the length thereof. The liner 17 reduces the inside diameter of the lumen 18 for a purpose hereinafter described. The liner 17 is made of a radiation stable material so that the catheter can be radiation sterilized. Tefzel, or Teflon FEP, which is a polymer is such a radiation sterilizable material. The inner liner 17 also serves to provide additional columnar strength to the catheter 12.

A wye adapter 21 is secured to the proximal extremity of the flexible tubular member 16. The side arm 22 of the adapter 21 has a stop cock 23 mounted therein which is movable between open and closed positions. The stop cock 23 is provided with a Luer fitting 24 which is adapted to be secured to a syringe which can be utilized for injecting a dye, or medications such as a vaso-dilator. The central arm 26 of the adapter 21 is connected to a Touhy Borst adapter 27 and includes a female part 28 that carries an o-ring 29 which is adapted to be engaged by a protrusion 31 forming a part of the male part 32.

The capsule catheter 12 has a capsule 36 incorporating the present invention mounted on the distal extremity of the flexible elongate tubular member 16. The capsule 36 when used in humans has a diameter ranging from 4 to 8 millimeters. The flexible elongate tubular member 16 which also serves as a shaft for advancing the capsule 36 as hereinafter described and should have a diameter which is less than that of the capsule and therefore has an outside diameter ranging from 3 to 7 millimeters.

The capsule 36 is a composite structure and is formed of an inner layer 37 and an outer layer 38. The inner layer 37 is formed of a stainless steel ribbon 39 with the ribbon having a width of 3.81×10^{-3}m (.;50 inches) and a thickness ranging from 5.08×10^{-5} - 1.016×10^{-4}m (.002 to .004 inches) and preferably approximately 7.62×10^{-5}m (.003 inches). The ribbon is spiral wound on a mandrel (not shown) so that each wrap of the ribbon overlaps the preceding wrap by approximately 30 to 50% of the width of the ribbon. Viewing the capsule 36 from the left hand end, the ribbon is wrapped in a clockwise or counterclockwise direction so that the edges 41 face distally or in the direction which is toward the right as shown in Figure 2 for a purpose hereinafter described. By winding the ribbon 39 at high tension, it is possible to deform it over the adjacent wrap which contributes to the flexibility of the capsule and also at the same time makes it possible to provide a capsule having a low profile. The stainless steel for the ribbon 39 can be of any suitable type, however, it has been found that it is desirable to select a stainless steel which can be heat treated. This enables one to wind the capsule with the ribbon in a ductile state and heat treat the capsule after winding to obtain a spring-like temper. One such stainless steel is 17-7 PH supplied by Brown Metals Company of Santa Fe springs, California.

In order to prevent elongation of the capsule 36 and also to prevent one wrap separating from another of the inner layer 37, a plurality of elongate flexible strands 43 are provided which extend from one end to the other of the capsule. It has been found that the use of four strands has been sufficient with the strands being spaced apart circumferentially by 90°. The strands 43 can be formed of a suitable material such as a Kevlar aramid fiber, 195 denier. These four strands 43 are bonded to the proximal and distal extremities of the capsule by a suitable adhesive such as a cyanoacrylate ester at points 44. The outer layer 38 which overlies the strands 43 and the wrapped ribbon inner layer 37 is in the form of a jacket formed of a suitable material such as heat shrinkable polyethylene. This jacket can have a wall thickness ranging from 2.54×10^{-5} - 1.524×10^{-4}m (.001 to .006

inches) and preferably a thickness of approximately 1.016×10^{-4}m (.004 inches). The polyethylene jacket which forms the outer layer 38 serves to contain the Kevlar strands 43 in close proximity to the inner layers 37 and also serves to prevent elongation of the capsule 36 while permitting the capsule to bend during use as hereinafter described. The outer layer or jacket 38 serves also to provide a smooth surface for the exterior of the capsule 36 by enclosing the edges 41 of the wraps of ribbon 39. In addition, the proximal and distal extremities of the capsule 36 are bonded together by a solder in the regions 46 as indicated in Figure 2. The solder can be of a suitable type, such as a tin silver solder comprised of 95% tin and 5% silver. When constructed in this manner, the capsule 36 can have an inside diameter of 4.445×10^{-3} - 7.62×10^{-3}m (.175 inches to .300 inches) with a nominal wall thickness of 3.048×10^{-5}m (.0012 inches).

The capsule 36 is secured to the distal extremity of the flexible elongate tubular member 16 by a capsule adapter 51 of a suitable material such as a polycarbonate. The capsule adapter 51 is secured in the proximal extremity of the capsule 36 by suitable means, as a press fit or alternatively, in addition, by the use of a suitable adhesive such as a cyanoacrylate ester. The other extremity of the capsule adapter 51 is also mounted in a suitable manner such as by a cyanoacrylate ester adhesive to the distal extremity of the flexible elongate tubular member 16. The capsule adapter 51 is provided with a hole 52 of a suitable diameter such as 1/16th of an inch.

The capsule 36 made in accordance with the present invention has a number of desirable features. It is particularly desirable because it is flexible and can be bent through an angle of 70 to 120° in a length of 8-20 centimeters. In order to prevent hangups on the inside edges 41 Of the ribbon, the inside edges are rounded and polished, preventing damage to capsule contents during ejection as hereinafter described. The Kevlar strands 43, which are also contained by the outer jacket or layer 38, serve to maintain the wrap, prevent stretching or elongation and prevent discontinuities from being formed in the capsule during use of the same. In addition, the Kevlar strands prevent the capsule from being flexed beyond a predetermined angle, as, for example, 120°.

Thus, it can be seen that a capsule 36 has been provided which is very flexible, yet is still very hard and has great strength which inhibits crushing or collapsing while being bent or flexed. In other words, it is kink resistant. It is also puncture proof due to the use of the metal ribbon 39. The capsule 36 is semi-radiopaque and is radiation sterilizable.

The endovascular grafting apparatus also includes a balloon catheter assembly 61 which consists of a shaft in the form of a flexible elongate element 62 formed of a suitable material such as irradiated polyethylene tubing extruded to a larger diameter of 4.064×10^{-3}m (.160 inches) outside diameter and 2.286×10^{-3}m (.090 inches) inside diameter and then reduced in size by heating and elongating the same to provide an inside diameter of 5.08×10^{-4}m (.020 inches) and an outside diameter of 1.27×10^{-5}m (.050 inches). However, the inside diameter can range from 3.81×10^{-4} - 6.35×10^{-4}m (.015 to .025 inches) and the outside diameter can range from 8.89×10^{-4} - 1.651×10^{-3}m (.035 to .065 inches) for a single lumen balloon catheter assembly. The single balloon inflation lumen 63 extends the length of the catheter. The catheter can have a suitable length as, for example, 50 to 130 centimeters. The lumen 63 can also serve as an injectate lumen and a pusher wire lumen as hereinafter described.

A separate balloon 64 formed of suitable material such as polyethylene is secured to the distal extremity of the flexible elongate member 62 in a manner hereinafter described. A pusher button 66 is provided which is formed of a suitable material such as 300 series stainless steel. The pusher button 66 can have a diameter ranging from 3.048×10^{-3} - 5.08×10^{-3}m (.120 inches to .200 inches) and preferably an outside diameter of approximately 3.556×10^{-3}m (.140 inches). Stainless steel is utilized to achieve radiopacity.

The pusher button 66 is mounted on a fixed position on the catheter shaft 62 and is spaced a predetermined distance from the proximal extremity of the balloon 64 as, for example, a distance of 2 to 3 centimeters. The pusher button 66 is retained in this position longitudinally of the shaft 62 by annular bulbs 67 and 68 which are formed by localized heating in those areas of the shaft 62 which causes it to expand radially in an attempt to achieve its original size to trap the pusher button 66 in that position on the shaft 62. Thus, it can be seen that the pusher button 66 can be mechanically trapped in place without the use of an adhesive and without changing the size of the lumen 63 which extends therethrough.

An alternative embodiment in which the pusher button 66 is movable between the proximal extremity of the balloon 64 and a single bulb 67 is shown in Figure 4.

A small stainless steel tube 69 is disposed within the balloon 64 and has its proximal extremity seated within the distal extremity of the shaft or flexible elongate member 62. The tube 69 has a suitable inside diameter such as 5.558×10^{-4}m (.022 inches), an outside diameter of 8.128×10^{-4}m (.032 inches) and a suitable length as, for

example, 7.5 centimeters. As can be seen from Figure 3, the tube 69 extends through the balloon 64 and terminates in the distal extremity of the balloon. The proximal extremity of the tube 69 is flared slightly so that it is firmly retained within the shaft 62 when the proximal extremity of the balloon is fused to the shaft 62 by the use of heat. The tube 69 serves to provide stiffness to the balloon 64 of the balloon catheter assembly 61 and is provided with a lumen 71 extending therethrough through which a fluid such as a gas or liquid can be introduced from the lumen 63 into the lumen 71 to inflate the balloon and to thereafter deflate the balloon 64 by withdrawing the gas or liquid. The balloon 64 can vary in diameter from 12 to 35 millimeters in diameter and can have a wall thickness ranging from 2.54×10^{-5} - 1.27×10^{-4}m (.001 and .005 inches). The polyethylene utilized for the balloon is irradiated to achieve an appropriate balloon size. One balloon made in accordance with the present invention had an outside diameter of 16 millimeters and had a wall thickness of approximately 7.62×10^{-5}m (.003 inches). In addition, the balloon when deflated is twisted into a helix and heated so as to provide it with a memory which facilitates its introduction into a vessel of a patient as hereinafter described.

A very flexible guide wire 74 is secured to the distal extremity of the balloon 64. The guide wire can have a suitable diameter such as 1.321×10^{-3}m (.052 inches) in outside diameter and con have a suitable length, as for example, 7 centimeters, The guide wire 74 can be a spring formed from wire having a suitable diameter such as 2.286×10^{-4}m (.009 inches) so that it will be radiopaque and thus readily observable under x-rays when being used. The guide wire is provided with a rounded tip 76 which can be formed from a suitable material such as a tin silver solder of 95% tin and 5% silver. The solder tip 76 has bonded therein the distal extremity of a safety ribbon 77 which extends towards the proximal extremity of the spring guide wire 74 and is secured to the proximal extremity thereof by suitable means such as the same tin silver solder hereinbefore described. The guide wire 74 can range in diameter from 9.144×10^{-4} - 1.524×10^{-3}m (.036 inches to .060 inches). The ribbon 77 can be formed of a suitable material such as stainless steel and have a thickness of 7.62×10^{-5}m (.003 inches) and a width of 2.54×10^{-4}m (.010 inches).

As can be seen from Figure 3, the proximal extremity of the spring guide wire 74 has been stretched longitudinally beyond the yield point so that there is a space or interstice between each turn of the wire forming the proximal extremity of the spring. A plug 78 of a non-irradiated polyethylene is placed within the proximal extremity of the spring guide wire 74 but remote from the distal extremity of the tube 69. The plug 78 and the distal extremity of the balloon 64 are then heated to cause the non-irradiated polyethylene to melt and flow into the interstices of the stretched spring 74 to bond the spring 74 to the distal extremity of the balloon 64 and to seal the distal extremity of the balloon so that gas cannot escape therefrom.

The guide wire 74 is easily observed using x-rays due to its width and stainless steel composition. Since the pusher button 66 is also formed of stainless steel, it also is an easy marker to follow. The pusher button 66 and guide wire 74 help indicate the position of the balloon 64 because the balloon 64 is positioned between the pusher button 66 and the guide wire 74. The balloon 64 itself can be observed under x-rays because the blood in the patient's vessel is more opaque than the gas used for inflating the balloon. However, increased visibility of the balloon 64 can be obtained by inflating the balloon 64 with a diluted radiopaque contrast solution. In addition, if desired as shown in Figure 3, two radiopaque bands 79 and 80 of a suitable material such as platinum or a platinum tungsten alloy can be placed on the proximal and distal extremities or necked-down portions of the balloon 64 to aid in ascertaining the position of the balloon 64.

It should be appreciated that although a separate balloon 64 has been provided, if desired, an integral balloon can be provided which is formed of the same tubing from which the flexible elongate tubular member 62 is made. This can be readily accomplished, as is well known to those skilled in the art, by using an additional radiation dose for the balloon region of the tubing.

In Figures 5 and 6 there is shown an alternative balloon catheter assembly 81 which utilizes a multi-lumen flexible shaft 82 having a balloon 84 secured to the distal extremity of the same. The flexible shaft 82 is provided with a guide wire lumen 86 of a suitable size, as for example, 1.016×10^{-3}m (.040 inches) which extends the entire length of the shaft and through the balloon 84. It is also provided with a balloon inflation lumen 87 of a smaller size such as 2.54×10^{-4}m - 3.81×10^{-4}m (.010 to .015 inches) which opens through a notched recess 90 into the interior of the balloon 84. The lumen 87 can be connected to a suitable syringe or other device for inflating and deflating the balloon 84. A pusher button 88 is mounted on the shaft 82 which is held in place by a bulb 89 formed on the shaft 82. A conventional guide wire 91 can then be inserted into the lumen 86 of the catheter assembly 81 and utilized in a conventional manner to advance the balloon catheter into tortuous vessels. Thus it can be seen that applicants' balloon catheter assembly 81 can be utilized in an over-the-

wire system which is commonly used in angioplasty. The proximal and distal extremities of the balloon 84 can be fused by heat to the shaft 82 so that the balloon 84 can be inflated and deflated. With the guide wire 91 removed the lumen 86 can be used as an injectate lumen.

The endovascular grafting apparatus also includes a pusher rod assembly 96 which is shown in Figure 7. It consists of a rigid thin wall tube 97 formed of a suitable material such as stainless steel. It has a suitable length as, for example, 21 centimeters and has an outside diameter of 1.651×10^{-3} m (.065 inches) and an inside diameter of 1.346×10^{-3}m (.053 inches). an elongate solid flexible wire 98 of a suitable diameter as, for example 4.572×10^{-4}m (.018 inches) is provided which extends centrally into the bore 99 of the tube for the entire length of the rigid tube 97. The wire 98 is secured by suitable means such as an adhesive into a male Luer cap 101 mounted on the proximal end of the tube 97.

The outside of the tube 97 is small enough so that it can slide inside the lumen sleeve 18 of the liner 17 of the catheter 12. The bore 99 of the rigid tube 97 is large enough so that it can receive the balloon catheter shaft 62 with the wire 98 extending into the lumen 63 of the shaft 62. The wire 98 is long enough so that it can extend through the balloon shaft 62 and through the balloon 64 and the tube 69 to engage the plug 78 provided at the distal extremity of the balloon 64. Typically, the pusher rod assembly 96 has a total length of approximately 75 centimeters.

An alternative pusher rod assembly 106 is shod in Figure 8 and consists of a rigid tube 107 similar to the tube 97 with a wire 108 having a diameter of, for example, 4.572×10^{-4}m (.018 inches) extending into the same and being connected to a male Luer cap 109. A Touhy Borst O-ring adapter 111 is secured to the proximal extremity of the tube 107 and is provided with an O-ring 112. A female Luer fitting 113 is mounted on the Touhy Borst adapter 111. In use of pusher rod assembly 106, the shaft 62 of the balloon catheter assembly 61 is threaded into the tube 106 over the wire 108 and through the o-ring 112. The proximal extremity of the shaft 62 is flared slightly over the o-ring after which the Touhy Borst adapter 111 can be tightened to seal the o-ring 112 around the balloon catheter shaft 62. After certain operations are accomplished as hereinafter described, the male Luer cap 109 and the wire 108 attached thereto can be removed and a syringe (not shod) can be placed on a female Liner adapter 113 to inflate the balloon.

An alternative embodiment of a pusher rod assembly 116 cooperating with the balloon catheter assembly 81 shown in Figure 5 is shown in Figure 9. The pusher rod assembly 116 is comprised of a flexible relatively rigid tubular sleeve 117 of stainless steel which has a bore of a diameter to accommodate the shaft 82 of the catheter assembly 81 through which the guide wire 91 extends. A wye adapter 118 is secured to the proximal extremity of the sleeve 117. A atop 119 is mounted in the aide arm of the adapter 118 and a Touhy Borst adapter 120 is mounted in the central arm of the adapter 118. The guide wire 91 extends through the guide wire lummen 86 and through the wye adapter 118 and the Touhy Borst adapter 120 so that it can be readily engaged by the hand for advancing and retracting the guide wire 91. The balloon 84 can be inflated and deflated through the stop cock 119. By pushing on the adapter 118 a force is applied to the pusher button 88 by the coaxial sleeve 117 for a purpose hereinafter described.

The endovascular grafting apparatus 11 also includes an expandable intraluminal vascular graft 121 shown in Figures 10 and 11 for implanting in a body vessel. The graft 121 consists of a deformable tubular member 122 which is provided with first and second ends 123 and 124 and a cylindrical or continuous wall 126 extending between the first and second ends 123 and 124. The continuous wall 126 can be woven of any surgical implantable material such as a Dacron-type 56 fiber. One material found to be satisfactory is DeBakey soft woven Dacron vascular prosthesis (uncrimped) sold by USCI. In order to prevent unravelling of the woven material at the ends, the ends can be melted with heat to provide a small melted bead of Dacron on each end. The tubular member 122 can have a suitable length as, for example, 8 to 15 centimeters with 10 centimeters being typical. The tubular member 122 can have a maximum expandable diameter ranging from 14 to 30 millimeters and a minimum diameter in a collapsed condition of 4.445×10^{-3} - 7.62×10^{-3}m (.175 to .300 inches). Expandable spring means 131 is provided on each of the first and second ends 123 and 124 off the tubular member 122 and is secured to the tubular member. The spring means serves to yieldably urge the tubular member 122 from a first compressed or collapsed position to a second expanded position. The spring means 131 is formed of a plurality of vees 132 with the apices 133 of the vees 132 being formed with helical coil springs 136 to yieldably urge the legs 137 and 138 of each off the vees 132 outwardly at a direction at right angles to the plane in which each of the vees lie. The spring moans 131 is shown more in detail in Figure 11 and as shown therein, the spring means is comprised of a single piece of wire which is formed to provide the vees 132 and also to define the helical coil springs 136 between the legs 137 and 138. In the construction shown in Figure 10, it

can be seen that the spring means 131 have apices lying in three longitudinally spaced-apart parallel planes 141, 142 and 143 which are spaced with respect to the longitudinal axis of the tubular member 122. The two ends of the single piece of wire can be welded together in one of the legs 137 and 138 to provide a continuous spring means.

The spring means 131 is secured to the first and second ends 123 and 124 of the tubular member by suitable means such as a Dacron polyester suture material 146 which is utilized for sewing the spring means onto the tubular member. This can be accomplished by a sewing operation with the suture material 146 extending into and out of the wall 126 of the tubular member and in which knots 147 are formed on each of the legs or struts 137 and 138 in such a manner so that the apices lying in the plane 141 extend outwardly and are spaced from the end on which they are mounted and in which the apices lying in the plane 142 extend just beyond the outer edge of the tubular member and in wnich the apices in tha third plane are positioned inwardly from the outer edge.

Hook-like elements 151 are provided on the apices lying in planes 141 and 142 and are secured to the vees 132 in the vicinity of the apices by suitable means such as welding. The hook-like elements 151 can have a suitable diameter such as 2.54×10^{-4} - 3.556×10^{-3}m (.010 to 0.14 inches) and a length from .5 to 3 millimeters. The hook-like elements are sharpened to provide conical tips. The hook-like elements 151 should have a length which is sufficient for the hook to penetrate into the vessel wall, but not through the vessel wall.

The spring means 131 with the hook-like elements 151 secured thereto are formed of a corrosion resistant material which has good spring and fatigue characteristics. One such material found to be particularly satisfactory is Elgiloy which is a chromium-cobalt-nickel alloy manufactured and sold by Elgiloy of Elgin, Illinois. The wire can have a diameter ranging from 2.54×10^{-4}m - 3.81×10^{-4}m (.010 to .015 inches) in diameter with the smaller diameter wire being utilized for the smaller diameter tubular members as, for example, 12 to 15 millimeters in diameter and the larger tubular members as, for example, those having a 30 millimeter diameter using the larger wire sizes.

It has been found that the spring force created by the helical coils 136 at the apices 133 is largely determined by the diameter of the wire. The greater the diameter of the wire, the greater the spring force applied to the struts or legs 137 and 138 of the vees. Also, the longer the distances are between the apices lying in planes 141 and 142, the smaller the spring force that is applied to the legs or struts 137 and 138. It therefore has been desirable to provide a spacing between the outer extremities of the legs or struts of approximately one centimeter, although smaller or larger distances may be utilized.

The hook-like elements 151 at the proximal and distal extremities of the graft 121 are angled at suitable angles with respect to longitudinal axis of the tubular member 122. The hook-like elements face towards each other to facilitate holding the graft 121 in place in the vessel of the patient. Thus, the hook-like elements 151 on the proximal extremity 123 are inclined from the longitudinal axis by 55° to 80° and preferably about 65° toward the distal end of the graft 121 in the direction of blood flow. The hook-like elements 151 on the distal end 124 of the graft or implant 121 are inclined from the longitudinal axis by 30° to 90° and preferably 85° in a direction towards the proximal end 123 and opposite the direction of blood flow. The hook-like elements 151 serve as attachment means at each end of the graft 121 and when implanted oppose migration of the graft.

The helical coil springs 136 placed at the nodes or apices 133 of the vees 132 of the spring means 131 serve to facilitate compression of the graft when it is desired to place the same within the capsule 36 as hereinafter described. The compression of the graft is accomplished by deformation of the coil springs 136 within their elastic limits. Placing the nodes or apices 133 in different planes greatly aids in reducing the size to which the graft can be reduced during compression of the same by staggering or offsetting the hooks or hook-like elements 151. This also helps to prevent the hook-like elements from becoming entangled with each other. The natural spring forces of the helical coil springs 136 provided in the spices of the vees serves to expand the graft to its expanded position as soon as the graft is free of the capsule 36. By way of example, as shown in the drawings, three spices or nodes can be provided in the plane 141 and three spice: or node: in the plane 142 which are offset longitudinally with respect to the nodes in plane 141 and six nodes in plane 143. The placement of six nodes or apices 133 in the plane 143 does not interfere with the compression of the graft 151 because there are no hook-like elements 151 at these nodes or apices 133 in the plane. For larger diameter grafts, the spring means 131 can be provided with additional apices or nodes 133 to enhance attachment as hereinafter described.

Radiopaque marker means is carried by the graft 121. The radiopaque marker means takes the form of four radiopaque markers 156. The radiopaque markers are made of a suitable material such as a platinum tungsten alloy wire of a suitable diameter such as 7.62×10^{-5}m (.003 inches which is wound into a spring coil having a diameter of

1.016×10^{-3}m (.040 inches) and having a length of 3.175×10^{-3}m (.125 inches). These markers 156 are secured to the tubular member 122 by the same suture material 146. Two of the radiopaque markers 156 are located on the tubular member 122 in spaced apart aligned positions longitudinally of and parallel to the longitudinal axis of the tubular member 122 but are adjacent to the apices 133 lying in the planes 143 at the opposite ends 123 and 124 of the graft 121. Thus the markers 156 are spaced a maximum distance apart on the graft but still within the attachment means carried by the graft 121. Another set of two markers is provided on the tubular member 122 spaced 180° from the first set of two markers along the same longitudinal axis (see Figure 15). By placing the markers in these positions, it is possible to ascertain the position of the graft 121 and at the same time to ascertain whether or not there has boon any twist in the graft between the first and second ends of the graft. In other words when there is no twist in the graft 121 the four markers 156 form four corners of a rectangle. However, if a twist in the graft 121 is present, then the pair of markers 156 at one end of the graft 121 have a different spacing transverse of the longitudinal axis of the graft then the other pair of markers 156 at the other end.

In order to ensure that the graft 121 will not become dislodged after it has been implanted, it may be desirable to provide alternative hook-like elements to ensure that the graft will remain in place after it has been implanted. An alternative hook-like element 161 is shown in Figure 12 in which each of the hook-like elements 161 has been provided with a barb 162 which extends outwardly from the main body 163 of the hook-like element. Thus by way of example, the main body 163 can be formed of a wire having a suitable diameter such as 3.048×10^{-4}m (.012 inches) with the diameter of the hook-like body in the vicinity of the barb 162 having a suitable diameter such as 2.54×10^{-4}m (.010 inches). The hook-like element can have a suitable length such as 1.5 millimeters

Another alternative hook-like element 166 is shown in Figure 13 which has a body 167 of a suitable diameter such as 2.54×10^{-4}m (0.10 inches) with a conical tip 168. Outwardly extending spring-like ribbons 169 having a suitable dimension such as 5.08×10^{-5}m (.002 inches) in thickness and a width of 2.032×10^{-4}m (.008 inches) are secured by suitable means such as velding to the body 167. As shown, the spring-like elements 169 can flare outwardly so that in the event any attempt is made to withdraw or retract the hook-like element, the spring-like ribbons 169 will become firmly imbedded in the tissue to inhibit such removal. It also should be appreciated that other means can be provided on the hook-like elements to inhibit withdrawal of the same from tissue once they have become embedded in the same. Thus, by way of example as shown in Figure 13, helical or annular serrations 170 can be provided on the book body to inhibit such withdrawal. In each of the embodiments with the hook-like elements it can be seen that the profile of the hook-like element is kept to a minimum during the time that it is penetrating the tissue.

The endovascular grafting apparatus 11 is shown assembled for use as shown in Figure 1 typically in the manner it would be packaged for shipment to a hospital or doctor for use. As shown in Figure 1, the graft has been compressed or squeezed onto the balloon shaft 62 and is positioned within the capsule 36 with the pusher button 66 being positioned immediately to the rear or proximal to the proximal extremity of the graft (see Figure 14) In this connection it should be appreciated in order to minimize the diameter of the graft to make use of a capsule of minimum diameter, the balloon catheter should be of minimum profile. The balloon shaft 62 is threaded on the wire 108 and extends into the rigid tube 107 of the pusher rod 106. The balloon 64 is disposed forwardly or distally of the capsule 36. The wire 108 is in engagement with the plug 78 in the distal extremity of the balloon 64.

When it is desired to perform a procedure utilizing an endovascular or system grafting apparatus 11 of the present invention to perform the method of the present invention, an apparatus is selected which has the appropriate size of graft 121 within the capsule 36. The length and size of the graft 121 is determined by the size of the vessel of the patient in which the aneurysm has occurred. Typically the size of the graft 121 is selected so that it has sufficient length to span approximately one centimeter proximal and one centimeter distal of the aneurysm so that the hook-like elements 151 of the graft can seat within normal tissue of the vessel on both sides of the aneurysm. Thus, the graft should be two centimeters longer than the aneurysm being repaired. The diameter is selected by measuring the vessel in a preimplant procedure by conventional radiographic techniques and then using a graft 121 of the next larger one millimeter size. During the preimplant fluoroscopy procedure, using a conventional pigtail catheter, the locations of the renal arteries are ascertained so that they will not be covered by the graft 121 when it is implanted.

Let it be assumed that the patient on whom the operation is to take place has been prepared in a conventional manner by use of a dilator with a guide wire and a sheath (not shown) to open the femoral artery or vessel of the patient. The apparatus 11 is inserted into the sheath which has pre-

viously been placed in the femoral artery of the patient. This insertion can be accomplished without a guide wire, with a guide wire or by the use of a soft sheath previously positioned over a guide wire . With the construction shown in Figure 3, the balloon 64 with its guide wire 74 followed by the capsule 36 is introduced into the femoral artery and advanced in the femoral artery by the physician grasping the proximal extremity of the capsule catheter 12 and the cap of the pusher rod assembly 96. The balloon 64 is twisted into a helix to place it in its helical memory condition to reduce its profile to a minimum. The balloon 64 and the capsule 36 are advanced by the physician into the desired position by use of the guide wire 74. The physician slightly rotates the apparatus 11 in the direction of the balloon twist to maintain the helical twist in the balloon 64 and pushes on the apparatus 11.

Typically a desired position will be within the abdominal aorta with the proximal extremity 123 of the graft 121 and at least one centimeter distal to the lower renal artery. At about the same time, the physician should rotate the capsule catheter 12 to rotate the capsule 36 and the graft therein in order to orient the radiopaque graft markers 156 such that the distance between the pair of markers 156 at each end of the graft 121 is maximized. As soon as the capsule 36 is in the desired position, the Touhy Borst O-ring assembly 27 is opened to permit free movement of the pusher rod assembly 96. With the balloon 64 riding well beyond or just distal of the end of the capsule 36, one hand of the physician is used for holding the pusher rod assembly 96 by engaging the cap 101 and holding the pusher rod stationary and pulling outwardly on the capsule catheter 12 with the other hand to cause relative movement between the pusher rod assembly 96 in the inner liner 17 and the capsule 36. This causes the wire 98 of the pusher rod assembly 96 to engage the plug 78 of the balloon catheter assembly 61. The pusher button 66 carried by the balloon catheter shaft 62 which is in engagement with the proximal extremity of the graft 121 in the region of the nodes 133 in the plane 143 forces the graft 121 out of the capsule 36 as the capsule is withdrawn. As soon as the proximal extremity of the graft 121 has cleared the distal extremity of the capsule, the proximal extremity 123 of the graft 121 pops outwardly under the force of the spring means 131 carried by the proximal extremity 123 of the graft 121 and will spring into engagement with the vessel wall 166.

As soon as this has occurred, the pusher rod assembly 96 is pulled out of the capsule catheter 12. While the physician uses one hand to hold the capsule catheter 12 stationary, the catheter shaft 62 which is protruding proximally of the capsule catheter 12 is grasped by the other hand and pulled rearwardly to position the proximal extremity of the balloon 64 into the proximal extremity 123 of the graft 121 as shown in Figure 15. A conventional hand operated syringe and Tuohy Borst adapter (not shown) are then taken and attached to the proximal extremity of the balloon catheter shaft 62. The balloon 64 is then expanded by introducing a suitable gas such as carbon dioxide or a dilute radiopaque liquid from the syringe to urge the hook-like elements 151 outwardly to firmly seat within the vessel wall 166.

As soon as this has been accomplished, the capsule catheter 12 is pulled out further with the balloon 64 still inflated until approximately one-half or more of the graft 121 has cleared the capsule 36. Leaving the balloon inflated provides additional security to insure that the proximally seated graft 121 will not move during retraction of the capsule 36. The balloon 64 is then deflated. The balloon 64 is then retracted further into the graft and reinflated to ensure that a good attachment is made between the hook-like elements 151 carried by the spring means 131 at the proximal extremity 123 of the graft 121. The capsule 36 can then be removed in successive steps and the balloon deflated, retracted and reinflated. The capsule catheter 12 can then be withdrawn completely to the distal portion of the abdominal aorta to permit the distal extremity 124 of the graft 121 to move out completely of the capsule 36 and to permit its distal extremity 124 to spring open and have the hook-like elements 151 move into engagement with the vessel wall 166. Thereafter, the balloon 64 is again deflated. The balloon catheter shaft is then grasped by the physician's hand and pulled rearwardly to center the balloon 64 within the distal extremity 124 of the graft 121. The balloon 64 is reinflated to set the hook-like elements 151 at the distal extremity of the graft into the vessel wall 166. As soon as this has been completed, the balloon 64 is again deflated. The balloon catheter assembly 61 is then removed from the femoral artery.

The entire procedure hereinbefore can be observed under fluoroscopy. The relative positioning of the graft 121 and the balloon 64 can be readily ascertained by the radiopaque attachment means 131, radiopaque markers 156 provided on the graft, and the radiopaque portions of the balloon 64. If any twisting of the graft 121 has occurred between placement of the proximal hook-like elements and the distal hook-like elements, this can be readily ascertained by observing the four markers 156. Adjustments can be made before ejection of the distal extremity 124 by rotation of the capsule catheter 12 to eliminate any twisting which has occurred. In addition, the distance between the pairs of radiopaque markers 156 longitudinal of the

axis is measured on the flat plate abdominal x-ray made during the procedure and compared with the known distance between the pairs of markers 156 longitudinal of the axis of the graft 121 ascertained during manufacture of the graft 121. This is done to ascertain whether longitudinal accordioning of the graft 121 has occurred.

Post implant fluoroscopy procedures can be utilized to confirm the proper implantation of the device by the use of a conventional pigtail catheter. Thereafter the sheath can be removed from the femoral artery and the femoral artery closed with conventional suturing techniques. Tissues should begin to grow into the graft within two to four weeks with tissue completely covering the interior side of the graft within six months so that no portion of the graft thereafter would be in communication with the blood circulating in the vessel. This establishes a complete repair of the aneurysm which had occurred.

It is apparent from the foregoing that there has been provided a new and improved endovascular grafting apparatus, system and method for utilizing the same. The construction of the capsule catheter is such that it has sufficient rigidity to ensure easy and ready placement of the capsule carried thereby. The pusher rod assembly which is used therein is constrained in such a manner so that relatively great forces can be applied to the pusher rod assembly even though the pusher wire has only a diameter of .018 inches. The tube 69 also serves to provide a confined space for the wire 98 to sit in while a high compressive force is being applied to the wire. The tube 69 prevents the wire from buckling or kinking within the balloon. It also prevents the balloon from collapsing during insertion of the apparatus 11. The capsule 36 which is provided as a part of the catheter assembly is formed of metal which makes it possible to utilize grafts having very sharp hook-like elements without any danger of them penetrating the capsule during the time that the capsule is being introduced into the vessel of the patient. In addition, the capsule since it is flexible and can bend through angles up to approximately 120° in order to readily negotiate the bends which occur in the vessel of the patient. The balloon catheter is made in such a way that the balloon can be readily introduced into the vessel because of the rigid tubular member provided within the balloon while at the same time permitting inflation and deflation of the balloon through the same tubular member. The pusher button 66 is mounted on the balloon catheter in such a manner so that it cannot shift at all in one direction or proximally longitudinally of the balloon catheter. The pusher button 66 also can only move a limited distance towards the balloon 64 until it reaches the balloon 64. In one embodiment shown in Figure 3 the pusher button 66 cannot move proximally or distally whereas in another embodiment shown in Figure 4 it cannot move proximally but can move distally. This is an advantage when retracting the proximal extremity of the balloon 64 into the graft 121 for placement of the proximal hook-like elements 151 because the pusher button 66 can slide forwardly or distally of the shaft 62 as the shaft 62 is retracted to bring the proximal extremity with the balloon 64 into the graft 121. Thus the pusher button 66 will not be pulled back into the capsule 36 and catch on the collapsed distal extremity 124 of the graft 121 within the capsule 36. The balloon is also mounted on the distal extremity of the balloon catheter in such a manner so that the balloon cannot leak. The balloon catheter can be provided with either a fixed guide wire, or if desired, a movable guide wire so that an over-the-wire system can be utilized,

The capsule 36 is constructed in such a manner so that it is semi-radiopaque allowing it to be visualized while still permitting observation of the graft within the capsule and the attachment means provided on the graft. The capsule 36 is also constructed in such a manner so that the hooks which are provided on the graft will readily slide in one direction over the wraps or turns of the capsule without hanging up or catching onto the individual wraps of the ribbon forming the capsule.

The graft which is provided with the helical coil springs at each of the nodes is particularly advantageous in that it permits compression of the graft into a very small size without causing permanent deformation of the attachment means. Because of the spring forces provided by the attachment means, it is possible that the grafts can be implanted without the use of an inflatable balloon for forcing the hook-like elements into the tissue of the vessel. However, at the present time, it is still believed to be desirable to utilize the balloon to ensure that the hook-like elements are firmly implanted into the wall of the vessel so as to inhibit migration of the graft within the vessel.

Claims

1. In an attachment system for securing a graft to a blood vessel, the attachment system including a sinusoidal wire frame having a plurality of longitudinally opposed apices and a plurality of lumen penetrating members, the invention comprising:

   configuring each apex with a helical coil spring configured to exert an outwardly directed bias on the wire frame.

2. The attachment system of claim 1, wherein said wire frame has a first end and a second

end, said first end being affixed to said second end to provide a continuous wire frame.

3. The attachment system of claim 2, wherein said first end is affixed to said second terminal end by a weld.

4. The attachment system of any of claims 1 to 3, wherein each of said plurality of lumen penetrating members include a generally longitudinally extending arm having a first end and a second end and outwardly protruding hooks extending radially outward from said first end.

5. The attachment system of claim 4, wherein said outwardly protruding hooks terminate with a sharpened conical tip.

6. The attachment system of claim 1, wherein said wire frame includes a plurality of struts, each of said struts connecting one of said plurality of longitudinally opposed apices to another of said plurality of longitudinally opposed apices.

7. The attachment system of claim 6, wherein each of said lumen penetrating members are individually affixed to one of said struts.

8. The attachment system of claim 7, wherein each of said lumen penetrating members are welded to said plurality of struts.

9. The attachment system of claim 1, wherein said wire frame is configured to be sewn to an inside wall of the graft.

10. The attachment system of any of the preceding claims, wherein each of said lumen penetrating members include a generally longitudinally extending arm having a first end and a second end and an outwardly protruding hook extending radially outward from said first end, said hook having a terminal end directed towards a plane perpendicular to a wall of the graft.

11. The attachment system of any of the preceding claims, wherein a first apex is longitudinally staggered from a second and adjacent apex.

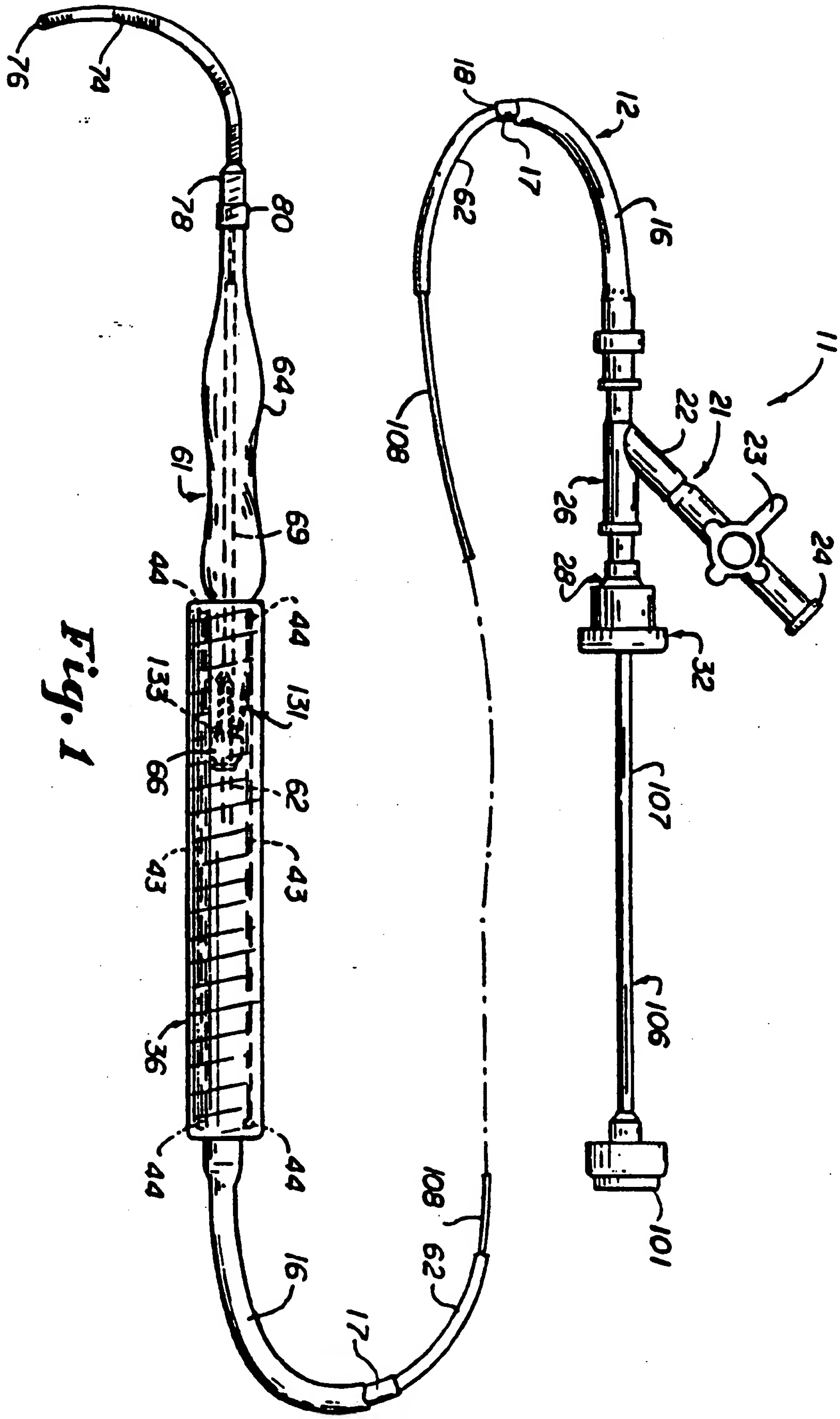
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Fig. 1

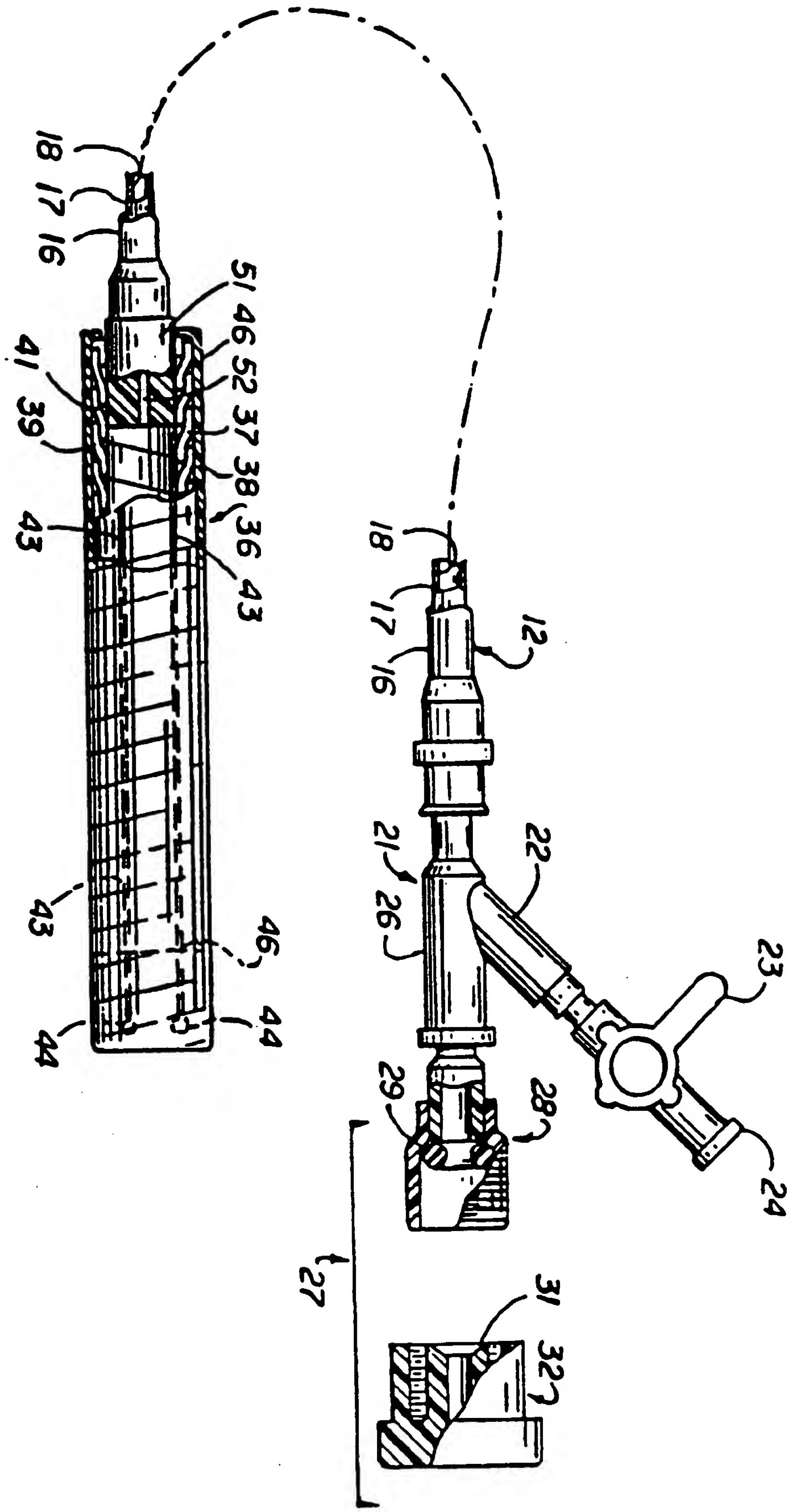
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Fig.2

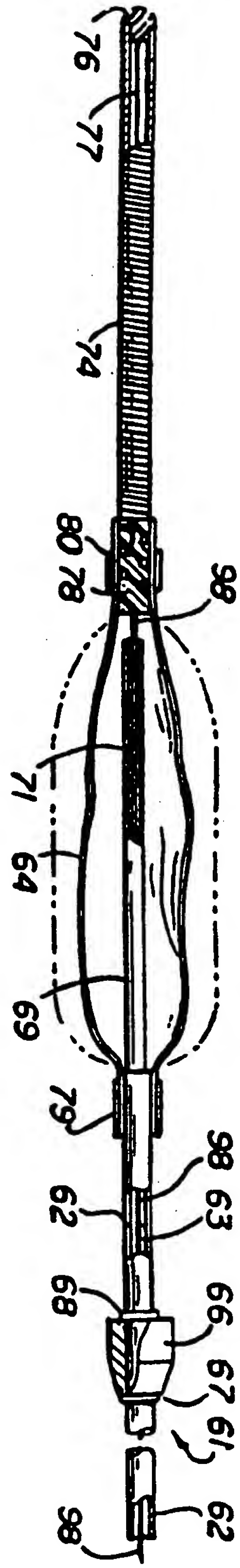

Fig.3

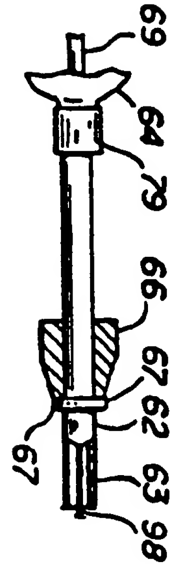

Fig.4

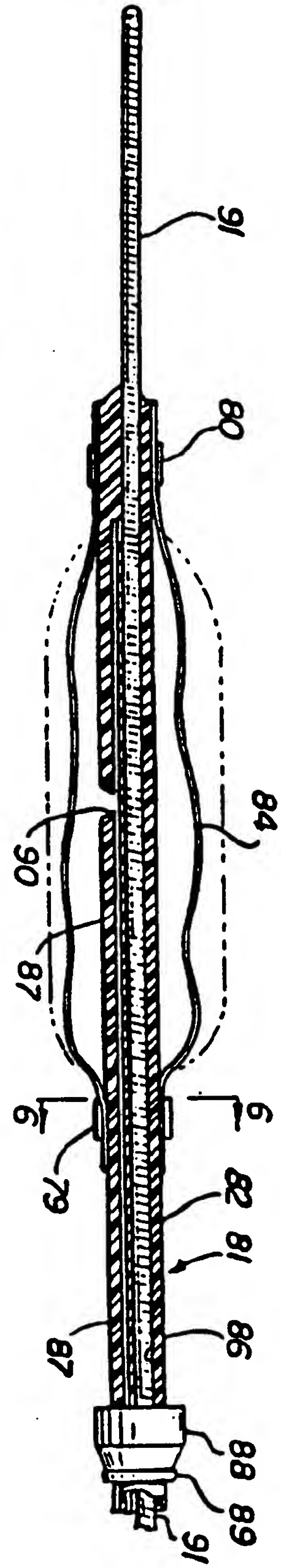

Fig.5

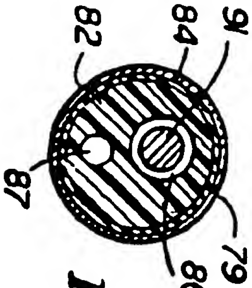

Fig.6

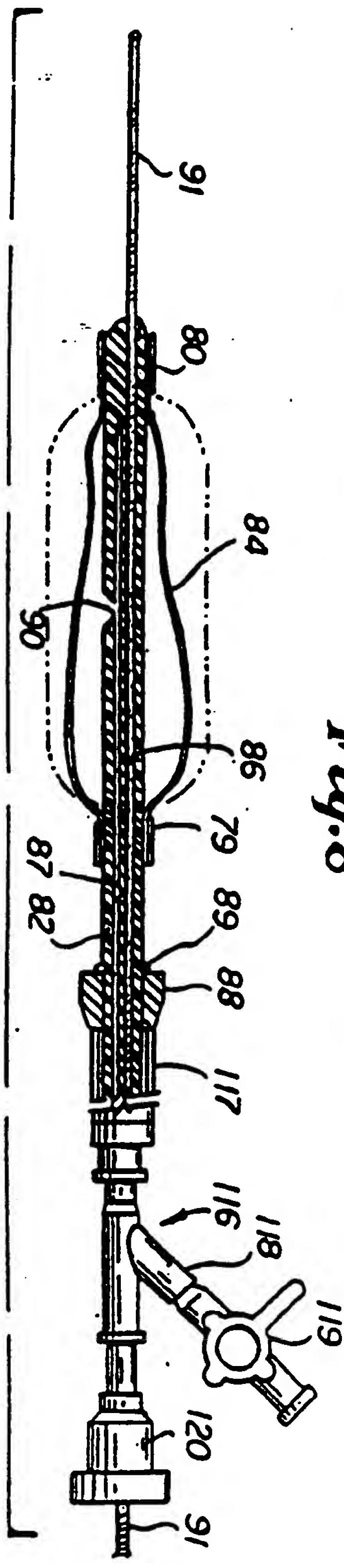

Fig. 9

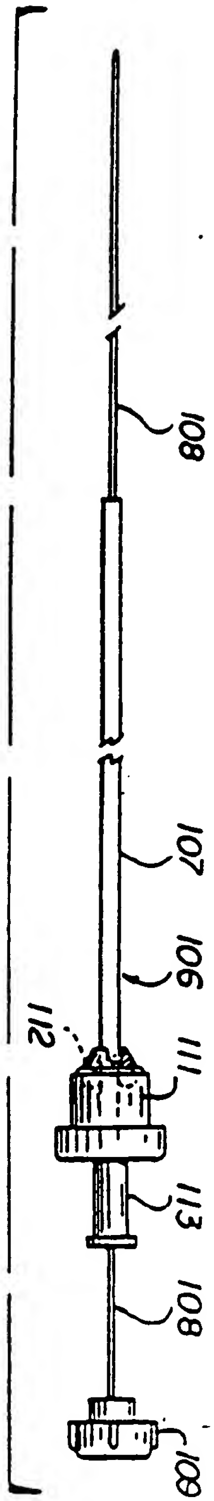

Fig. 8

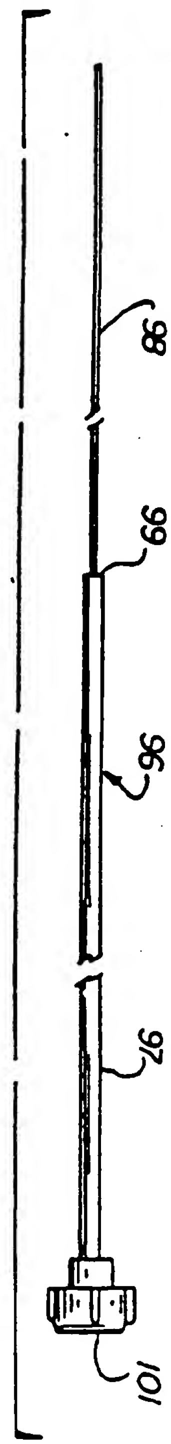

Fig. 7

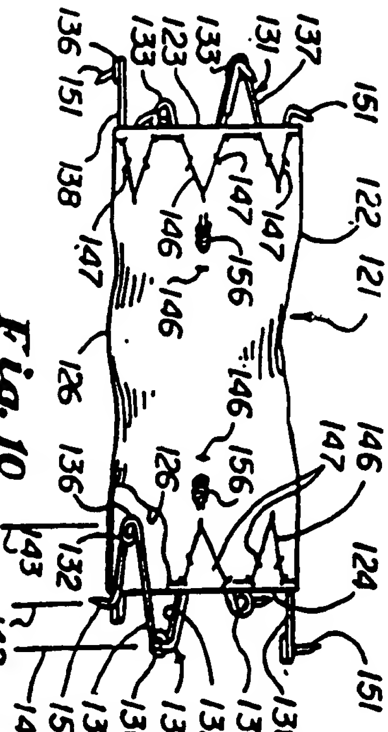

Fig.10

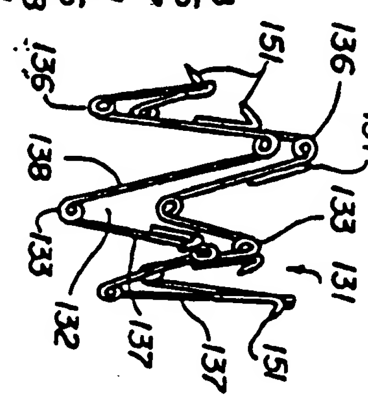

Fig.11

Fig.12

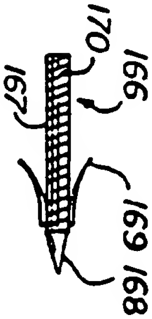

Fig.13

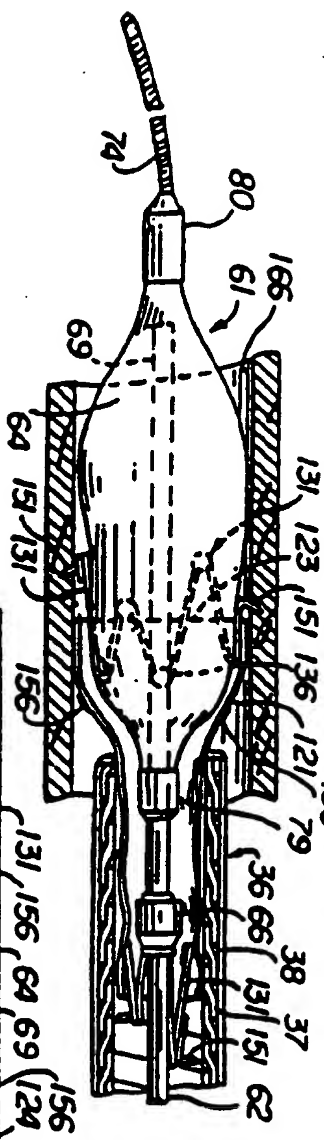

Fig.14

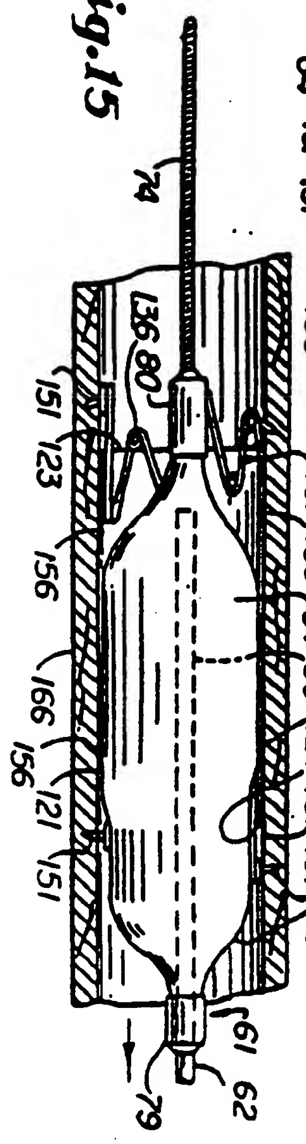

Fig.15